Enar

Naproxen + Esomeprazole

COMPOSITION:

Enar 375 Tablet: Each tablet contains delayed release Naproxen BP 375 mg and immediate release Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 20 mg.

Enar 500 Tablet: Each tablet contains delayed release Naproxen BP 500 mg and immediate release Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 20 mg.

PHARMACOLOGY:

Enar consists of an immediate release Esomeprazole Magnesium layer and an enteric coated Naproxen core. As a result Esomeprazole is released first into the stomach, prior to the dissolution of Naproxen in the small intestine. Naproxen is an NSAID with analgesic and antipyretic properties. Naproxen inhibits the synthesis of Prostaglandin. Esomeprazole is a proton pump inhibitor that suppresses gastrin acid secretion by specific inhibition of the H^+/K^+- ATPase in the gastric parietal cell. By acting specifically on the proton pump Esomeprazole blocks the final step in acid production, thus reduces gastrin acidity.

INDICATION:

It is indicated for the relief of signs and symptoms of osteoarthritis, rehumatoid arthritis and ankylosing spondylitis, dysmenorrhoea and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.

DOSAGE AND ADMINISTRATION:

Enar 375 once or **Enar** 500 tablet twice daily.

The tablets are to be swallowed whole with liquid. Do not split, chew, crush or dissolve the tablet. The tablet is to be taken at least 30 minutes before meals.

Elderly patients: Studies indicate that although total plasma concentration of Naproxen is unchanged, the unbound plasma fraction of Naproxen is increased in the elderly. Use caution when high doses are required and some adjustment of dosage may be required in elderly patients. As with other drugs used in the elderly use the lowest effective dose.

Patients with renal impairment: Naproxen containing products are not recommended for use in patients with moderate to severe renal impairment (creatinine clearance < 30 ml/min).

Hepatic insufficiency: Not recommended in patients with severe hepatic impairment because Esomeprazole dose should not exceed 20 mg daily in these patients.

Children: Use in children less than 18 years has not been established yet.

CONTRAINDICATION:

- Known hypersensitivity to any component of **Enar** or substituted benzimidazoles.
  History of asthma, urticaria or other allergic-type reactions after taking aspirin or other NSAIDs.
  Use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery.
  Late pregnancy.

SIDE EFFECTS:

Most common side effects are erosive gastritis, dyspepsia, gastritis, diarrhea, gastrin ulcer, upper abdominal pain, nausea etc.

PRECAUTIONS:

Patients with known CV disease/risk factors may be at greater risk. **Enar** should be used with caution in patients with fluid retention or heart failure.

USE IN PREGNANCY AND LACTATION:

In pregnancy: Pregnancy category C. In late pregnancy, it should be avoided because it may cause premature closure of the ductus arteriosus.

In lactation: **Enar** should not be used in nursing mothers due to the naproxen component.

DRUG INTERACTIONS:

- Concomitant use of NSAIDs may reduce the antihypertensive effect of ACE Inhibitors, diuretics, and beta-blockers.
- Concomitant use of **Enar** and warfarin may result in increased risk of bleeding complications.
- Esomeprazole inhibits gastric acid secretion and may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (eg, ketoconazole, iron salts and digoxin).

OVERDOSAGE:

There is no clinical data on overdosage with **Enar**.

Overdose of Naproxen: Significant naproxen overdosage may be characterized by lethargy, drowsiness, epigastric pain, abdominal discomfort, heartburn, indigestion, nausea, transient alterations in liver function, hypoprothrombinemia, renal dysfunction, metabolic acidosis, apnea, vomiting etc.

Overdose of Esomeprazole: The major signs of acute toxicity were reduced motor activity, changes in respiratory frequency, tremor and intermittent clonic convulsions etc.

PHARMACEUTICAL PRECAUTION:

Enar tablet should be stored at a cool and dry place, protect from light and moisture.

HOW SUPPLIED:

Enar 375 Tablet: Each box contains 28 tablets in Alu-Alu blister pack.

Enar 500 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.

Manufactured by:

MEDICON

MEDICON Pharmaceuticals Ltd.

Mirpur, Dhaka, Bangladesh